RECEIVED AT DRUG SAFETY SURVEILLANCE
19-FEB-1998-0662

McNEIL CONSUMER PR
FORT WASHINGT

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Individual Safety Report
3031679-7-00

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
Case 199 In confidence	60 yrs or Date of birth:	(X) female ( ) male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

(x) death unknown (mo/day/yr)
( ) life-threatening
(x) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event: unknown (mo/day/yr)

4. Date of this report: 02/09/98 (mo/day/yr)

5. Describe event or problem

Case # 199 received from the [redacted]996 case fatality data.
See attached case report form provided by [redacted]

6. Relevant tests/laboratory data, including dates

See attached case report form provided by [redacted]

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

See attached case report form provided by [redacted]

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Unknown acetaminophen product
#2

2. Dose, frequency & route used
#1 "large amounts", po
#2

3. Therapy dates (if unknown, give duration) (from/to (or best estimate))
#1 unknown dose or duration
#2

4. Diagnosis for use (indication)
#1 unknown
#2

5. Event abated after use stopped or dose reduced
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)
#1 Unknown
#2

7. Exp. date (if known)
#1 Unknown
#2

8. Event reappeared after reintroduction
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)
See attached case report form provided by [redacted]

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)
( ) foreign
( ) study
(x) literature
( ) consumer
(x) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr): 01/30/98

5. (A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)
( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) Initial ( ) follow-up #

8. Adverse event term(s)
OVERDOSE INTENT
COMA
LIVER FAILURE
RESPIRATORY DIS
HYPOTENSION
PROTHROMBIN INC
CREATININE INC
DEATH

9. Mfr. report number: 0929697A

E. Initial reporter

1. Name, address & phone #
[redacted]MD
[redacted]Centers
[redacted]Suite[redacted] Avenue
[redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	physician	( ) Yes ( ) No (X) Unk

FDA
Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

[redacted] TESS FATALITY: 1996 [redacted]

Case Number: 199

Age:	60 yrs
Substances:	Acetaminophen
Chronicity:	Unknown
Route:	Ingestion
Reason:	Unknown
Pre-Hospital Arrest?	No

Patient was a 60-year-old female who was brought to the emergency department after being found unresponsive at home with evidence of ingesting "large amounts" of acetaminophen at an unknown time. The poison center was consulted one day after admission to the ICU. At the time of initial consultation, the patient was comatose with fulminant hepatic failure, ARDS and hypotension. Her acetaminophen level at the time of admission was 89 mcg/ml. The patient's liver enzymes peaked at AST = 25,254 IU/L. Protime, ammonia, bilirubin, BUN, creatinine were also markedly elevated. The patient was treated with N-acetylcysteine, dopamine, vitamin K and hemodialysis. However, the patient remained comatose, hypotensive and developed worsening respiratory failure. Aggressive treatment was withdrawn by the patient's family two days after her admission and the patient expired the following day.